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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,079	06/22/2001	Signe Erickson Varner	55821 (71699) 6574	
21874	7590 03/09/2006		EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874			DESANTO, MATTHEW F	
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.   Applicant(s)   App								
### Examiner   Art Unit   3763    ### The MAILING DATE of this communication appears on the cover sheet with the correspondence address  **Period for Reply**  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  **Extension of their may be available under the protestons of 3° CPR 1.136(s). In one event, however, may a reply be timely filed in the cover of their part of the cover of the cove		Application No.	Applicant(s)					
Matthew F. DeSanto The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.		09/888,079	VARNER ET AL.					
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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - and STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - and STATUTORY CONTROL TO THE ADMINISTRATION OF THIS COMMUNICATION.  - and STATUTORY CONTROL TO THE ADMINISTRATION OF THIS COMMUNICATION.  - Falure to right yellow the set or extended period for right with, by statute, cause the application to become ASANDONED (30 U.S. 5, 13.3).  - Falure to right yellow the set or extended period for right with, by statute, cause the application to become ASANDONED (30 U.S. 5, 13.3).  - Falure to right yellow the set or extended period for right with, by statute, cause the application to become ASANDONED (30 U.S. 5, 13.3).  - Falure to right yellow the set or extended period for right with yellow the control of this communication, even if limitly filed, may reduce any secreted patent term adjustment. Set 37 CFR 1.704(s).  - Status  - This action is FINAL.  - 2b) This action is filed on 19 November 2005.  - 2a) This action is FINAL.  - 2b) This action is filed on 19 November 2005.  - 2a) This action is FINAL.  - 2b) This action is filed on 19 November 2005.  - 2a) This action is filed on 23.35.38.41.47 and 49.79 is/are pending in the application.  - 4a) Of the above claim(s) is/are withdrawn from consideration.  - 5a) Claim(s) 23.35.38.41.47 and 49.79 is/are rejected.  - 7b) Claim(s) is/are allowed.  - 6b) Claim(s) 23.35.38.41.47 and 49.79 is/are rejected.  - 7c) Claim(s) is/are objected to.  - 8b) Claim(s) is/are objected to by the Examiner.  - 8b) The specification is objected to by the Examiner.  - 8c) The specification is objected to by the Examiner.  - 8c) The specification is objected to by the Examiner.  - 8c) The specification is objected to by the Examiner.  - 8c) The specification is objected to by the Examiner.  - 8c) This action the specification is objected to by th			L					
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of mem say be available under the proximator of 37 cFR 11360, in no event, however, may a pely be timely filled after 30 x (6) MONTHS from the mailing date of this communication of 15 x (6) MONTHS from the mailing date of this communication of 15 x (6) MONTHS from the mailing date of this communication of 15 x (6) MONTHS from the mailing date of this communication of 15 x (6) MONTHS from the mailing date of this communication. Pallute to repy within the set of centended parted for repy will, by statistic, ease the application to December ABMONDED 15 x (13 x	The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
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a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  Attachment(s)    Notice of References Cited (PTO-892)	Priority under 35 U.S.C. § 119							
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Attachment(s)  1) Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Attachment(s)  Interview Summary (PTO-413) Paper No(s)/Mail Date  Notice of Informal Patent Application (PTO-152)	application from the International Bureau (PCT Rule 17.2(a)).							
Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  A) Interview Summary (PTO-413) Paper No(s)/Mail Date  Notice of Informal Patent Application (PTO-152)		2 222 3363						
Paper No(s)/Mail Date  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Notice of Informal Patent Application (PTO-152)	Attachment(s)							
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  5) Notice of Informal Patent Application (PTO-152)								
	3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) 🔲 Notice of Informal P						

#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 23, 24, 27-31, 38, 49, 51, 52, 54, 60, 61, 63, 64, 65, 67, 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Palasis et al. (USPN 6,969,371).

Palasis et al. discloses the use of a medical device for treating the eye (see claims 1, 2, 6, 10) and having a piercing member (30) and a cannula (26) that administers a fluid into the body (see figure 6C, claims 2, 10 and entire reference)

3. Claims 23-35, 38, 42-47, 49-52, 55-65, 70-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Cupler, II (USPN 4,002,169).

Cupler, II discloses a method of performing surgery on the eyes with using an incision, wherein the device has a piercing member (118) and a cannula (140, 150), wherein the piercing member pierces the eye and the cannula is advanced to the treatment site to remove a cataract or the like (Figure 3, 8, 9, 11, 18 and entire reference).

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## Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 23-35, 38, 41-47, 49-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cupler II and further in view of Paques et al. (US Pub 2003/0171722) view of Bowman et al. (USPN 6,378,526).

Cupler II discloses the claimed invention except for what specific therapeutic agents can be applied to the eye as well as explicitly disclose the particulars of the location of where the needle will be able to treat.

Paques et al. discloses a method for treating an eye with a device comprising a piercing member (4) with an outer diameter less than 25 gauge (0053) allowing the puncture location to self-seal and having a flexible plastic tube therein (0087) to administer a therapeutic substance to the eye. The device is used to treat conditions such as vascular occlusion (0039) by advancing the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally (Figure 1, 2, 3 and paragraph [0105]-[0113]). Paques et al. also teaches more specific methods of injecting fluid into the eye.

Bowman et al., teaches a device for delivery of a therapeutic agent such as steroids, genetic material, or pharmaceuticals to the eye.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to deliver follow the steps of Paques et al. when injecting fluid into the eye when performing retina surgery, as well as using several of the different therapeutic agents that are taught by

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Paques et al. and Bowman et al., since this is well known in the art to use different doses and medications depending on the procedure and treatment.

### Response to Arguments

6. Applicant's arguments filed 11/29/05 have been fully considered and are persuasive. Therefore the past 102 and 103 rejections have been withdrawn and a new set of rejections have been made.

#### Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto

Art Unit 3763 March 6, 2006